

All prior rejections have been withdrawn. The new issues raised by the present Action are addressed hereinbelow.

I. Objection of Claim 64

Applicants note that the Action states on form PTO-326 under the heading "Disposition of Claims", item 7), that "claim(s) 64 is/are objected to". However, no further discussion on this point is made in the Action. Therefore, the nature of the objection cannot be determined. If this objection is maintained, Applicants respectfully request that the reasons be stated so that a proper response to this objection can be made.

II. Rejection under 35 U.S.C. §112, First Paragraph

Claims 60, 62 and 65-87 are newly rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

In support of the rejection, the Examiner first contends that there is not sufficient evidence that Applicants were in possession of the (1) "infinite number of molecules" or (2) "plethora of ... antagonists" which would inhibit angiogenesis as claimed, and further states that there is not evidence of "all the antagonists capable of arresting angiogenesis". This argument is respectfully traversed because failure to recite every possible species under a genus is not, of itself, a reason to deny a claim that recites a generic element.

The present invention is directed to a method of inhibiting angiogenesis, and includes as one of the recited

elements the step of administering a composition comprising an $\alpha_v\beta_5$ antagonist. The invention is not a description of a "plethora" of $\alpha_v\beta_5$ antagonist compounds, but rather is a method which uses a generic reagent identified as an $\alpha_v\beta_5$ antagonist. Applicants are not claiming any $\alpha_v\beta_5$ antagonist as the invention, but rather are claiming the use of any of a large number of species of $\alpha_v\beta_5$ antagonist in the claimed method. Applicants were in possession of the invention because a method was conceived which uses a generic reagent, and at the time the invention was made, had conceived and described a number of different species under the generic reagent which could be used in the claimed method.

Applicants argue that they are not required to disclose every species encompassed by the claims. *In re Fisher*, 166 USPQ 18 (CCPA 1970). Applicants submit that "what the Patent Office is here attempting is to limit the claims to the specific examples, notwithstanding the disclosure of a broader invention. This it may not do." *In re Anderson*, 176 USPQ 331, 333 (CCPA 1973).

Applicants submit that they are in possession of the invention of a method of inhibiting angiogenesis as claimed using the generic reagent, an $\alpha_v\beta_5$ antagonist. There is no requirement that every species be named, so long as one skilled in the art knows how to make and use the invention. Applicants have stated in the specification that any $\alpha_v\beta_5$ antagonist can be used in the claimed method.

Applicants assert that the specification teaches how to make and use an $\alpha_v\beta_5$ antagonist having the claimed characteristics and that one of ordinary skill in the art would have known how to practice the claimed invention without undue experimentation.

In traversing this rejection, Applicants direct the Examiner's attention to the specification where antagonists of $\alpha_v\beta_5$ are broadly as well as specifically described with respect to structural and functional characteristics, such enablement beginning at page 23, continuing to page 34. In particular, Applicants cite to Example 6 as exemplary teachings of the enablement of a number of different $\alpha_v\beta_5$ antagonist compounds including cyclic peptides, antibodies and MMP-2 fragments in functioning to significantly inhibit angiogenesis in a number of different experimental models. Thus each different kind of antagonist molecule will function in the claimed method, so long as it is an $\alpha_v\beta_5$ antagonist. There is no basis under the patent statutes to limit an invention simply because the genus element of an " $\alpha_v\beta_5$ antagonist" reads on an allegedly "infinite" or "plethora" amount of species, if one skilled in the art can make and use an $\alpha_v\beta_5$ antagonist according to the claimed method.

The present rejection is similar to denying a claim to a mechanical process in which one of the mechanical elements is a generic fulcrum, where the specification gives several examples of a suitable fulcrum means, but does not provide an exhaustive list of every species of fulcrum. It is not appropriate to deny the generic method claim because an inventor does not disclose every possible species of fulcrum, which species is just one element of the method claim.

In addition, the specification in Example 7 teaches how to identify and screen an $\alpha_v\beta_5$ antagonist that is useful in the present invention. Therefore, not only does one skilled in the art know what an $\alpha_v\beta_5$ antagonist is, but the specification teaches one skilled in the art how to recognize an $\alpha_v\beta_5$ antagonist.

In *Amgen Inc. v Hoechst Marion Roussel, Inc and Transkaryotic Therapies, Inc.*, 2003 U.S. App. LEXIS 118, decided January 6, 2003, the court upheld the claims because "the claim terms at issue here are not new or unknown biological material that ordinarily skilled artisans would easily miscomprehend." The claims in Amgen's patents referred to mammalian and vertebrate cell types that could be used to express recombinant human EPO. The court found that the words "mammalian" and "vertebrate" conveyed distinguishing information that was readily understood by one of ordinary skill in the art. In the present claims, it is submitted that the term " $\alpha_v\beta_5$ antagonist" is readily understood by one of ordinary skill.

The second argument put forth by the Action states that "a number of antibodies may possess a high affinity for the $\alpha_v\beta_5$ but not be effective in inhibiting angiogenesis". This position is respectfully traversed because the ground for rejection is not clear.

The statement in the Action supporting the rejection is misleading because it ignores a recited claim element. The claim reads " $\alpha_v\beta_5$ antagonist", not "antibody with affinity for $\alpha_v\beta_5$ ". Applicants have not claimed a method using any molecule with an "affinity for $\alpha_v\beta_5$ ". The molecule that satisfies the generic claim element must be an antagonist, not merely a molecule that binds to $\alpha_v\beta_5$ with some affinity. If this rejection is maintained, clarification is respectfully requested.

Finally, there are a few points to be clarified. Firstly, the Action mentions "oligonucleotides" as an example of an

antagonist that is not disclosed with any evidence; however, Applicants have not disclosed or claimed that an "oligonucleotide" is an $\alpha_v\beta_5$ antagonist. Secondly, the Action states that "the specification only suggest mAb P1F6 and mAb P5H9 effective in inhibiting angiogenesis"; however, the specification actually specifically discloses that many antibodies can function as an $\alpha_v\beta_5$ antagonist in the claimed method, not just these two antibodies. Finally, the Action states that the specification does not disclose "any cyclic polypeptides and organic mimetic compounds effective in inhibiting angiogenesis"; however, the specification does disclose cyclic peptides (at page 24, line 14; page 25, lines 12-15; page 26, lines 2-4; page 27, lines 18-19 and 31-32; page 32, line 26; page 39, line 4, lines 14-18, and line 22; pages 40-41; and page 50, lines 3-6) and does disclose organic mimetic compounds (at pages 65-87) which can inhibit angiogenesis according to the claimed methods (see page 19, lines 11-27). In view of the specific support identified, it is requested that these points stand on the record as having been clarified.

For the above reasons, Applicants submit that the rejections for alleged failure to convey that the inventors possessed the invention has been overcome as to the remaining pending claims to the methods of inhibiting angiogenesis with an $\alpha_v\beta_5$ antagonist. As such, Applicants respectfully request that the rejections be withdrawn and the claims pass on to allowance.

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III. Summary

Applicants believe that a complete response is provided in the foregoing remarks to each grounds for rejection raised by the Examiner. Applicants submit that patentable subject matter exists with regard to the pending claims and therefore respectfully request favorable action and entry of the presents Amendments and Response. The application is now believed to be in proper condition for allowance and early notification of allowance is earnestly solicited. The Examiner is invited to telephone the undersigned if it would be deemed helpful to advance the application.

Respectfully submitted,

JANUARY 30, 2003

Date

A handwritten signature in dark ink, appearing to read "Thomas Fitting".

Thomas Fitting, Reg. No. 34,163

THE SCRIPPS RESEARCH INSTITUTE
Office of Patent Counsel
10550 North Torrey Pines Road
Mail Drop TPC-8
La Jolla, California 92037
(858) 784-2937

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